

101



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,290	04/16/2002	Detlef Hasse	DAVI149.001APC	1731

7590 06/15/2004

KNOBBE, MARTENS, OLSON & BEAR
 620 NEWPORT CENTER DRIVE
 SIXTEENTH FLOOR
 NEWPORT BEACH, CA 92660

EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
----------	--------------

1648

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,290

Applicant(s)

HASSE ET AL.

Examiner

Zachariah Lucas

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-8, 10, 11, 13, 14 and 17-39 is/are pending in the application.
- 4a) Of the above claim(s) 22-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8, 10, 11, 13, 14, 17-21, and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/16, 8/12, 8/22/02.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group 1 in the paper filed October 22, 2003 is acknowledged. The traversal is on the ground(s) that there is no undue burden on the office in the examination of the different inventions in the present application. This is not found persuasive because separate searches are required for each of the separately claimed inventions, and because separate issues are involved in the examination of the different inventions.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 22-38 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper filed October 22, 2003.

3. Currently, claims 1-4, 6-8, 10, 11, 13, 14, 17-21, and 39 are pending and under consideration.

Information Disclosure Statement

4. The information disclosure statements (IDS) submitted on April 16, August 12, and August 22, 2002, are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Art Unit: 1648

5. It is noted that The IDS of April 16, 2002 cites PCT WO 97/20040 as a reference. However, this reference does not appear relevant to the claimed inventions. Further, the Applicant has submitted a copy of WO 97/20050, which does appear relevant, with the IDS. It is assumed that this is the reference the Applicant intended to make of record. For the purposes of expediting prosecution, the later WO reference has been made of record in the attached form PTO 892.

6. Applicant's citation of Barker et al. is noted. However, the reference has only been considered to the extent of the submitted pages (i.e. pages 1-37 of the reference).

7. Copies of the following references cited in the August 12, 2002 IDS were not submitted with the IDS:

Ausubel et al., "Current Protocols in Molecular Biology" Alan R Bliss Inc.

Cole et al., Monoclonal Antibodies in cancer therapy.

Dayhof, M.D. Nat. Biomed. Res. Found.

Gabriel et al., Vaccines, 95 (1995).

McPherson et al., A Practical Approach.

Sambrook et al., Molecular Cloning: A laboratory manual in the IDS or August 12, 2002.

Thus, the Applicant has not met the requirements under 37 CFR 1.98 for these references. They have therefore been crossed out from the IDS and have not been considered.

Specification

Art Unit: 1648

8. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the specification of the application does not provide antecedent basis for the claim limitations in claims 21 and 39. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-4, 6-8, 10, 11, 13, 14, 17-21, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims read on isolated or recombinant polypeptides, or compositions thereof, of the OmpH protein from *Lawsonia* spp., and in particular, polypeptides from *L. intracellularis*. However, it is not clear what is meant by an *L. intracellularis* polypeptide, or, by extension, what is included as a *Lawsonia* spp. polypeptide.

The Applicant has defined the term "*L. intracellularis*" as including "all microorganisms similar to or otherwise related to this microorganism." App., page 1, lines 22-26. However, the Applicant has provided no means by which those in the art can determine the scope of what is meant by the phrase "similar to or otherwise related." It is noted that the Applicant has referred to a number of references. However, while these references disclose bacterial species that may be "otherwise related" to *L. intracellularis*, the references also appear to consider such other organisms as other than *L. intracellularis* (i.e. would not consider the single name to encompass all

Art Unit: 1648

of the disclosed bacterial organisms). See e.g., McOrist et al., page 824. In view of such, and because the Applicant has not specified the extent of similarity or other relatedness required in order for an organism to be considered an *L intracellularis* cell as defined by the Applicant, the extent of what is being claimed is not clear from the specification or the claim language.

Further the specification and the claims indicate that *L intracellularis* is a subgenus within the genus identified as *Lawsonia* spp. Because it is unclear what the extent of the subgenus of *L intracellularis* is, but also appears that the Application considers the term to extend beyond what the art teaches as the *Lawsonia* genus, it is also unclear what the Applicant considers to fall within the scope of *Lawsonia* spp, and therefore of *Lawsonia* spp. polypeptides.

The claims are therefore rejected as indefinite.

11. Claims 6-8, 10, 11, 17, 18, 21, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claim read on either "a peptide, oligopeptide or polypeptide comprising an amino acid sequence which has at least about 70% sequence identity to the amino acid sequence set forth in SEQ ID NO: 1, " or on a "polypeptide having at least about 70% sequence identity" to SEQ ID NO: 1. The claims are rejected for two reasons.

First, it is unclear if the claim quoted claim language requires that the claimed peptides or polypeptides comprise at least 70% of the sequence of the full length of SEQ ID NO: 1, or if the claims require only that the polypeptides share at least 70% identity with the residues in the sequence of SEQ ID NO: 1 corresponding to the polypeptide.

Art Unit: 1648

Second, it is unclear what the distinction is between the terms "peptide," "oligopeptide," and "polypeptide" in the first quoted phrase.

Clarification is required.

12. Claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims read on the vaccine composition according to claim 16 of the application. However, claim 16 was cancelled from the application in the amendment of November 13, 2001. It is therefore not clear what is being claimed.

For the purposes of this action, these claims are treated as depending from claim 17.

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 1-4, 6-8, 10, 11, 17, 18, 21, and 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic polypeptides of SEQ ID NO: 1, does not reasonably provide enablement for any variant or homologue thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims read on any immunogenic polypeptide "comprising a Lawsonia spp. OmpH polypeptide,

Art Unit: 1648

a variant, or a truncated variant thereof, wherein said variant or truncated variant mimics or cross-reacts with a B-cell or T-cell epitope of *Lawsonia* spp. OmpH polypeptide.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered.

In the present case, it is first noted that the claims read broadly not only on variants or homologues of the full length protein of SEQ ID NO: 1, but also read on fragments and epitopes of SEQ ID NO: 1, and on variants and mimics of such fragments. Thus, the claims are broadly drawn. In contrast to this breadth, the Applicant has provided only a single example of the inventions falling within the claim language- SEQ ID NO: 1 itself. There is no disclosure of any fragments of SEQ ID NO: 1, nor is there any identification of epitopes of any kind from within the sequence. Further, the Applicant has provided no guidance or information as to what residues of the sequence may be mutated so as to retain the ability to cross-react with antibodies to SEQ ID NO: 1, or as to what sequences may act as mimics to epitopes within the sequence.

In the art of protein modification, it is accepted that the effects of such mutation is not generally predictable. See e.g. Bowie et al., *Science* 247: 1306-10 (indicating the unpredictability

Art Unit: 1648

of even a single substitution in a protein sequence on the protein's function). Further, it is also known in the art that the change of a single amino acid change may change a peptide/protein's immunogenic properties. See e.g., Riffkin et al., Gene 279-83 (teaching that a single amino acid change between two proteins was sufficient to create antigenically different proteins). See also, Pinilla et al., Mol Immunol 30(6): 577-85 (teaching that the effect of substitutions within protein epitopes is variable and cannot be predicted absent knowledge of the functional importance of the residue and structural information regarding the epitope's association with an antibody). Thus, the art teaches that the effects of making changes to an amino acid sequence are unpredictable, and that such changes may, without further information than the sequence alone (e.g. essential residues), result in a change in the proteins ability to interact with a protein specific antibody.

Furthermore, the Applicant has also indicated that those in the art would be able to easily determine the positions of epitopes within SEQ ID NO: 1. However, while the Applicant points to several references which provide means for predicting possible epitopes, these references do not teach that such means are fully reliable. For example, on page 588 of the Meister et al. reference (Vaccine 13: 581-91- of record in the August 12, 2002 IDS), the reference states "Not all predicated epitopes can be expected either to bind to MHC molecules with high affinity, or to simulate immune responses both in vitro and in vivo." The reference also states "The only true test of the predictive power of the [described] algorithms will be in the synthesis and in vitro testing of predicted epitopes." Thus, the reference teaches that, while those in the art are in possession of useful methods for the prediction potential epitopes within a protein, the art itself is still unpredictable as to the ability of any particular predicted epitope to actually perform as

Art Unit: 1648

required, and that the final determination as to the ability of the peptides to work requires experimental data. Thus, by not providing any information regarding antigenic sites within the protein, the Applicant has left it to those in the art to discover for themselves what sequences within SEQ ID NO: 1, or its variants, would be effective anti-L intracellularis epitopes.

Furthermore, even if it is assumed that the Applicant has provided an enabling disclosure with reference to epitopes within SEQ ID NO: 1, the Applicant has not provided any information with reference to the modification of such epitopes or mimics of such epitopes such that they are enabled for variants thereof. See *supra*, describing the unpredictability in the art of protein modification. The application is therefore not enabling for variants of mimics of polypeptides of SEQ ID NO: 1 that cross react with immune molecules directed against the disclosed sequence.

For all of these reasons, the teachings in the specification are not found to provide sufficient information such that those in the art can make or use polypeptides according to the claims without undue experimentation.

15. Claims 1-4, 6-8, 10, 11, 17, 18, 21, and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As was described above, these claims read on any immunogenic polypeptide "comprising a *Lawsonia* spp. OmpH polypeptide, a variant, or a truncated variant thereof, wherein said variant or truncated variant mimics or cross-reacts with a

Art Unit: 1648

B-cell or T-cell epitope of Lawsonia spp. OmpH polypeptide. Thus, the claims read broadly on a genus including any OmpH polypeptide from any Lawsonia spp. bacterium.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Accordingly, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed.

In the present application, the Applicant has provided only a single example of a Lawsonia spp. OmpH polypeptide- the L intracellularis protein of SEQ ID NO: 1. While the Applicant has provided examples of other OmpH proteins (Figure 3), these polypeptides do not appear to share at least 70% identity with SEQ ID NO: 1, and have been indicated by the Applicant to be distinct from the L intracellularis protein. See e.g., page 24 lines 21-30, and page 58, lines 3-15 (indicating the sequences of Figure 3, other than that of SEQ ID NO: 1, to be from other pathogens, and that the alignment demonstrates the distinctness of SEQ ID NO: 1 from the other proteins). Thus, the Applicant has provided only a single example of an L

Art Unit: 1648

intracellularis OmpH protein. Because the Applicant has not provided any examples of homologues or variants of the protein that mimics or cross-reacts with antibodies to SEQ ID NO: 1, the Applicant has not provided adequate written description for the genus comprising any *Lawsonia* spp., or any homologue or variant of any *Lawsonia* spp or *L intracellularis* OmpH protein.

Further, the Applicant has not identified any B- or T-cell epitopes of SEQ ID NO: 1. Rather, the only descriptive support provided for this genus is the identification of the peptides as epitopes, and the assertion that those in the art would be able to identify such epitopes. See e.g., App. page 9, lines 24-32. However, the Federal Circuit has stated that, to satisfy the written description requirement, the Applicant must provide a description of the claimed genus by providing, for example, "a representative number of species" actually reduced to practice," or by identifying a set of "functional characteristics coupled with a known or disclosed correlation between function and structure." Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406. In either case, the court stated, "when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus." The court also specifically stated that functional language alone was insufficient to describe a genus of inventions. On page 1406 of the Eli Lilly decision, the CAFC stated:

It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Thus, more than the identification of desired function for the claimed invention is required.

Art Unit: 1648

In the present case, while the claims are broadly drawn to any "B-cell or T-cell epitope" of any *Lawsonia* spp. OmpH polypeptide, or variants or mimics thereof, the Applicant has not provided a single example of such an epitope. Nor has the Applicant provided any correlation between any sequence within SEQ ID NO: 1, and the ability of that sequence to act as an epitope to the OmpH protein. In view of the lack of examples or correlation of a particular structure to the functional characterization as an epitope, the specification does not provided adequate written description support for the claimed genus of inventions.

16. Claims 3, 8, 10, 17-21, and 39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic polypeptides or compositions comprising a peptide of an *L intracellularis* OmpH protein, does not reasonably provide enablement for any polypeptides of SEQ ID NO: 1, or derivatives thereof, capable of inducing a protective immune response or for vaccines comprising such polypeptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The claims read on polypeptides or compositions (including vaccines) comprising polypeptides of an *L intracellularis* OmpH protein which induce a protective immune response.

The claims broadly read on any sequence comprising SEQ ID NO: 1, or any fragment, derivative, or homologue thereof that induces a protective immune response against *L intracellularis*, and *L. app. bacterium*, or (in view of the Applicant's definition of *L intracellularis*) any "similar or otherwise related" bacterium. However, while the Applicant has provided the protein sequence of SEQ ID NO: 1, the Applicant has neither provided any

Art Unit: 1648

evidence that the protein is capable of inducing a protective immune response against the bacterium, or identified any epitopes, fragments, or derivatives of the sequence that would be so capable.

The art indicates that little is known, even recently, about the structure and function of the *L intracellularis* bacterium, or the pathogenesis of the bacterium. See e.g., McCluskey et al., *Infect Immun* 32(8): 1980-85. Further, the reference additionally teaches that those in the art have had difficulty studying the bacterium due to its intracellular nature. *Id.*, at pages 2900 and 2904. See also, Guedes et al., *Vet Microbiol* 91(2-3): 135-45 (teaching that little is known about the immune responses against the virus); and Guedes et al., *Vet Microbiol* 93(2): 159-66, esp. page 160 (teaching difficulties involved in the extraction and maintenance of the bacterial cells for study). Thus, the art teaches that the field of technology, that of the pathology and treatment of infections by this bacterium is complex in nature, and is not well understood.

It is further noted that there is very little art referring to the vaccination of mammals against infection by this bacterium (see e.g. IDS references, generally focusing on the detection, and not the prevention of infection.) Further, the only demonstration of a protective vaccine against the bacterium to date appears to have been using attenuated whole bacteria, and not using subunit vaccines. See e.g., Guedes, *Vet Microbiol* 91: 135-45; and U.S. Patent 5,885,823, columns 17-25. See also, Kroll et al., *AM J Vet Med* 65(5): 559-65, at 559 (teaching that as of 2004, non-live *L intracellularis* vaccines had "resulted in equivocal results," and noting that killed and subunit vaccines of intracellular species had been largely unsuccessful despite numerous trials). The art provides no teachings or guidance indicative that the claimed polypeptide would be useful in anti-*L intracellularis* vaccines. Further, the art also indicates that

Art Unit: 1648

the use of subunit vaccines against intracellular species has been largely ineffective, thereby providing evidence of further complexity and unpredictability in the art.

In view of the limited data provided in either the art or the application regarding the use of bacterial proteins in the treatment of infection by *L. intracellularis*, the breadth of the claims, and lack of working examples of the claimed inventions in the application, the Applicant has not provided sufficient information to enable those in the art to make and use the claimed inventions without undue experimentation.

17. Claims 13, 14, and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is a rejection for **Deposit without a promise for availability**. The nucleic acid in the pALK13 plasmid is required to practice the claimed invention. This is because, the Applicant has claimed inventions comprising the polypeptide encoded by the sequence of the plasmid, and has not provided the sequence in the application. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the claimed/described plasmid. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining the plasmid and it is not apparent if it is readily available to the public. Applicant's deposit statement on specification

Art Unit: 1648

page 59 does not indicate the extent of public availability. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

18. Claims 21 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims read on a combination of the *L intracellularis* OmpH protein with another antigen of that bacterium. However, the prior art does not appear to provide any teachings as to other specific proteins for the *L intracellularis* bacterium, and the present application provides no identification of such other proteins. It is noted that original claim 39 refers to such antigens, however, such antigens do not appear to have been known in the art at the time of filing, and have not been described in the present application other than by the names provided in the claim. The Applicant is therefore not enabled for compositions comprising such antigens.

19. Claims 21 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

Art Unit: 1648

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims have been described above. As was indicated above, the Applicant has provided no written description support for these claims to compositions including other polypeptide antigens of L intracellularis. The only reference in the present application to such other polypeptides is in claims 21 and 39. While the Applicant has referred to such proteins by name in claim 39, there is not indication that those in the art at the time of filing would have understood this reference, or been able to determine from the specification what proteins were being referred to. In view of the lack of examples of other L intracellularis proteins in either the art or the application, the Applicant has not provided adequate written description support for the claimed inventions

Conclusion

20. No claims are allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas
Patent Examiner



JAMES HOUSEL 6/13/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600